



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2012-0911; FRL-9398-9]

#### Quinoxifen; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of quinoxifen in or on multiple commodities which are identified and discussed later in this document. This regulation also deletes the established tolerances in or on grape; pepper, bell; pepper, nonbell; and strawberry as they will be superseded by crop group/subgroup tolerances established by this tolerance rule. The Interregional Research Project Number 4 (IR-4) Project Headquarters requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0911, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm.

3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0911 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0911, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of Wednesday, January 16, 2013 (78 FR 3377) (FRL-9375-4), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8117) by IR-4 Project Headquarters, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.588 be amended by establishing tolerances for residues of the fungicide quinoxyfen, 5,7-dichloro-4-(4-fluorophenoxy)quinoline, in or on berry, low growing, subgroup 13-07G at 0.90 parts per million (ppm); fruiting, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 0.60 ppm and vegetable, fruiting, group 8-10 at 1.7 ppm. In addition, the petition requested removal of established tolerances in or on grape at 0.60 ppm; strawberry at 0.90 ppm; pepper, bell at 0.35 ppm; and pepper, nonbell at 1.7 ppm, as these will be superseded upon approval of the proposed tolerances. That document referenced a summary of the petition prepared by Dow AgroSciences LLC, the

registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA has revised proposed tolerance levels for several commodities and revised the quinoxifen tolerance expression for all established commodities. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for quinoxifen including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with quinoxifen follows.

### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The primary target organs affected by quinoxifen are the liver and kidney. The most sensitive species was the rat. Liver effects were seen in the subchronic rat and mouse studies as well as the chronic dog study. Subchronic effects observed in rats and mice at high doses included increased liver weights, hepatocellular hypertrophy, and individual cell hepatocellular necrosis. Chronic effects observed in the dog included increased liver weights, increased alkaline phosphatase levels, and increased incidence of very slight to slight microscopic hepatic lesions. Kidney effects were noted in the rat combined chronic/carcinogenicity study that resulted in an increased severity of chronic progressive glomerulonephropathy in males. Body-weight decrements were seen in the rat and/or mouse subchronic, chronic and carcinogenicity studies as well as the rabbit developmental and rat reproduction studies.

Oral rat and rabbit developmental studies showed no increased qualitative or quantitative susceptibility of offspring to quinoxifen *in utero*. In the rabbit developmental toxicity study, maternal and developmental toxicity were observed at the highest dose tested (HDT) (lowest-observed adverse-effect level; LOAEL = 200 mg/kg/day). Maternal effects included inanition (exhaustion due to lack of nourishment), clinical signs, decreased body weight and body-weight gains, decreased food

consumption, and increased incidence of abortion late in pregnancy. Developmental toxicity was evidenced as increased incidence of abortion late in pregnancy. No maternal or developmental toxicity was observed in the rat developmental study up to the limit dose of 1,000 mg/kg/day. In the 2-generation rat reproduction study, no parental effects were observed up to the HDT (100 mg/kg/day) while first-generation pup weights were reduced at the same dose. There is apparent quantitative susceptibility when looking at the 2-generation reproductive study in isolation, but when using a weight-of-evidence approach that puts the offspring findings in the 2-generation reproduction toxicity study in context with the full toxicological database there is no concern for susceptibility to offspring since it is anticipated that parental toxicity would have been observed at the same dose (see Unit III.D.2).

No evidence of neurotoxicity or neuropathology was seen in any of the submitted studies.

A 28-day immunotoxicity study showed no evidence that quinoxifen elicits an immunotoxic response up to the HDT.

The EPA has classified quinoxifen as “not likely to be carcinogenic to humans” based on no evidence of carcinogenicity in rat or mice studies. Moreover, quinoxifen did not show evidence of mutagenicity in *in vitro* or *in vivo* studies.

Specific information on the studies received and the nature of the adverse effects caused by quinoxifen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document: “Quinoxifen. Human-Health Risk Assessment for the Proposed Uses on Vegetable, Fruiting, Group 8-10; Fruit, Small Vine Climbing,

Except Fuzzy Kiwifruit, Subgroup 13-07F; and Berry, Low Growing Subgroup 13-07G,” dated August 20, 2013, pp. 27 – 30 in docket ID number EPA-HQ-OPP-2012-0911.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

Following is a summary of the “Dose-Response Assessment” with the appropriate toxicological endpoints used if available from the human health risk assessment.

1. *Acute dietary endpoint (all populations)*. There were no adverse effects observed attributable to a single dose for the general population (including infants and



children) or females 13-49 years of age; therefore, an acute RfD and PAD were not calculated for this exposure scenario.

2. *Chronic dietary endpoint (all populations).* The chronic RfD (cRfD) was established based on the NOAEL (20 mg/kg/day) from the rat combined chronic toxicity/carcinogenicity study. The LOAEL of 80 mg/kg/day in this study is based on increases in severity of chronic progressive glomerulonephropathy in the males and minimal decreases in body weight and body-weight gain in both sexes. The NOAEL of 20 mg/kg was chosen because the study and endpoint are appropriate for the route and duration of exposure. The cPAD of 0.2 mg/kg/day is derived from the NOAEL of 20 mg/kg/day and a 100-fold uncertainty factor (10X for interspecies extrapolation, 10X for intraspecies variation, and 1X for FQPA SF).

3. *Cancer classification.* The Agency classified quinoxifen as “not likely to be carcinogenic to humans” by all routes of exposure based upon lack of evidence of carcinogenicity in rats and mice.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to quinoxifen, EPA considered exposure under the petitioned-for tolerances as well as all existing quinoxifen tolerances in 40 CFR 180.588. EPA assessed dietary exposures from quinoxifen in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one-day or single exposure. No such

effects were identified in the toxicological studies for quinoxifen; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID), ver. 3.16 which incorporates consumption data from the United States Department of Agriculture (USDA) 2003 – 2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEA). The unrefined chronic analysis assumed 100 percent crop treated (PCT), DEEM 7.81 default concentration factors, and tolerance-level residues for all existing and proposed crop uses.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that quinoxifen does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for quinoxifen. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for quinoxifen in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of quinoxifen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the First Index Reservoir Screening Tool (FIRST) for surface water, and the Screening Concentration in Ground Water (SCI-GROW) models for ground water, the estimated drinking water concentrations (EDWCs) of quinoxifen for chronic exposure, assessments are estimated to be 0.66 ppb for surface water and for ground water, the estimated drinking water concentration is 0.0034 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 0.66 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Quinoxifen is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found quinoxifen to share a common mechanism of toxicity with any other substances, and quinoxifen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that quinoxifen does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a

common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Oral rat and rabbit developmental studies showed no increased qualitative or quantitative susceptibility of offspring to quinoxifen *in utero*. In isolation, there is evidence of increased quantitative susceptibility in the 2-generation reproduction toxicity study. No parental effects were observed up to the HDT (100 mg/kg/day) while first-generation pup weights were reduced at the same dose.

Concern is low since:

i. The effects in pups are well characterized with a clear NOAEL of 20 mg/kg/day.

ii. The pup effects are minimal at the LOAEL and only noted in the first-generation offspring.

iii. The doses and endpoints selected for regulatory purposes would address concerns for the pup effects noted in the rat reproduction study.

Additionally, taking into consideration the full toxicological database, there would be no susceptibility to offspring since assessments to parental animals are intentionally limited in the 2-generation reproduction study to avoid stressing dams and affecting the rearing and care of offspring. If additional evaluations had been performed on parental animals in the 2-generation reproduction study, including histopathology and organ weight assessments, then it is expected that the kidney and liver effects observed in the rat subchronic oral study and in the interim (12 months) and final sacrifices of the rat chronic toxicity/carcinogenicity study would have been seen at the 100 mg/kg/day dose in the reproduction study. Therefore, when using a weight-of-evidence approach that puts the offspring findings in the 2-generation reproduction toxicity study in context with the full toxicological database there is no concern for susceptibility to offspring since it is anticipated that parental toxicity would have been observed at the same dose.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF is reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for quinoxyfen is complete.
- ii. There is no indication that quinoxyfen is a neurotoxic chemical based on available acute and subchronic neurotoxicity studies. EPA determined that there is no need to require a developmental neurotoxicity study or apply additional uncertainty factors to account for neurotoxicity.
- iii. Using the full toxicological database, there is no indication that quinoxyfen will result in increased susceptibility to offspring (see Unit III.D.2).

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues, and DEEM 7.81 default processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to quinoxifen in drinking water. These assessments will not underestimate the exposure and risks posed by quinoxifen.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure and no acute dietary endpoint was identified for any segment of the United States (U.S.) population. Therefore, quinoxifen is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to quinoxifen from food and water will utilize 8.5 % of the cPAD for children 1-2 years old the population group receiving the greatest exposure. There are no residential uses for quinoxifen.

3. *Short-term and intermediate-term risks.* Short-term and intermediate-term aggregate exposure takes into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Quinoxifen is not registered for any use patterns that would result in residential exposure. Therefore, the short-term and intermediate-term aggregate risk is the sum of the risk from exposure to quinoxifen through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, quinoxifen is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to quinoxifen residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate gas chromatography/mass-selective detector (GC/MSD) method is available for enforcing quinoxifen tolerances (DowElanco Procedure ERC95.26); a successful petition method validation (PMV) has been completed. The lowest level of method validation (LLMV) was 0.01 ppm. Samples from the submitted field and processing studies were analyzed using a high-performance liquid chromatography/mass spectrometry (HPLC/MS) method derived from Dow AgroSciences Report RF 98-200 dated May 31, 1999; method entitled “Determination of Residues of Quinoxifen Applied as EF-1295 in Hops.” The LLMV was 0.01 ppm for quinoxifen in all tomato matrices.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

*B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

Codex MRLs are established for residues of quinoxifen per se in/on grapes, strawberries, and peppers. EPA is raising the level of the requested U.S. tolerances for residues of quinoxifen in/on the berry, low growing subgroup 13-07G and the fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F in order to harmonize with the Codex MRLs. Harmonization of the requested U.S. tolerance for residues of quinoxifen in/on the vegetable, fruiting, group 8-10 (1.7 ppm) with the Codex MRL for peppers (1 ppm) is not possible because residue data from field trials conducted in the U.S. with quinoxifen show that residues levels resulting from use of quinoxifen under the existing U.S. registration on peppers may exceed the Codex MRL.



### *C. Revisions to Petitioned-For Tolerances*

EPA increased the proposed tolerance levels for fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F and berry, low growing, subgroup 13-07G to 2.0 ppm and 1.0 ppm, respectively, in order to harmonize with international Codex maximum residue limits (MRLs). EPA relied on Organization for Economic Co-operation and Development (OECD) tolerance-calculation procedures and the submitted residue data sets in establishing these tolerances.

In addition, EPA revised the quinoxyfen tolerance expression to clarify:

1. That, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of quinoxyfen not specifically mentioned; and
2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

### **V. Conclusion**

Therefore, tolerances are established for residues of quinoxyfen (5,7-dichloro-4-(4-fluorophen oxy)quinoline) in or on berry, low growing, subgroup 13-07G at 1.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 2.0 ppm; and vegetable, fruiting, group 8-10 at 1.7 ppm.

### **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not

subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In

addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 9, 2013.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.588 amend paragraph (a) as follows:

i. Revise the introductory text,

ii. Remove entries for commodities: “Grape”; “Pepper, bell”; “Pepper, nonbell”;

and “Strawberry”, and

iii. Alphabetically add the following commodities to the table.

The additions read as follows:

**§ 180.588 Quinoxifen; tolerance for residues.**

(a) *General.* Tolerances are established for residues of the fungicide quinoxifen, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only quinoxifen (5,7-dichloro-4-(4-fluorophenoxy)quinoline).

Commodity	Parts per million
* * *	* *
Berry, low growing, subgroup 13-07G	1.0
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2.0
* * *	* *
Vegetable, fruiting, group 8-10	1.7

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[FR Doc. 2013-22597 Filed 09/17/2013 at 8:45 am; Publication Date: 09/18/2013]